



# Long-Term Follow-up in NORDIC-BALTIC Bifurcation Studies



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# Disclosure Statement of Financial Interest

I, *Indulis Kumsars*, DO NOT have a financial interest/arrangement or affiliation with one or more organizations that could be perceived as a real or apparent conflict of interest in the context of the subject of this presentation.

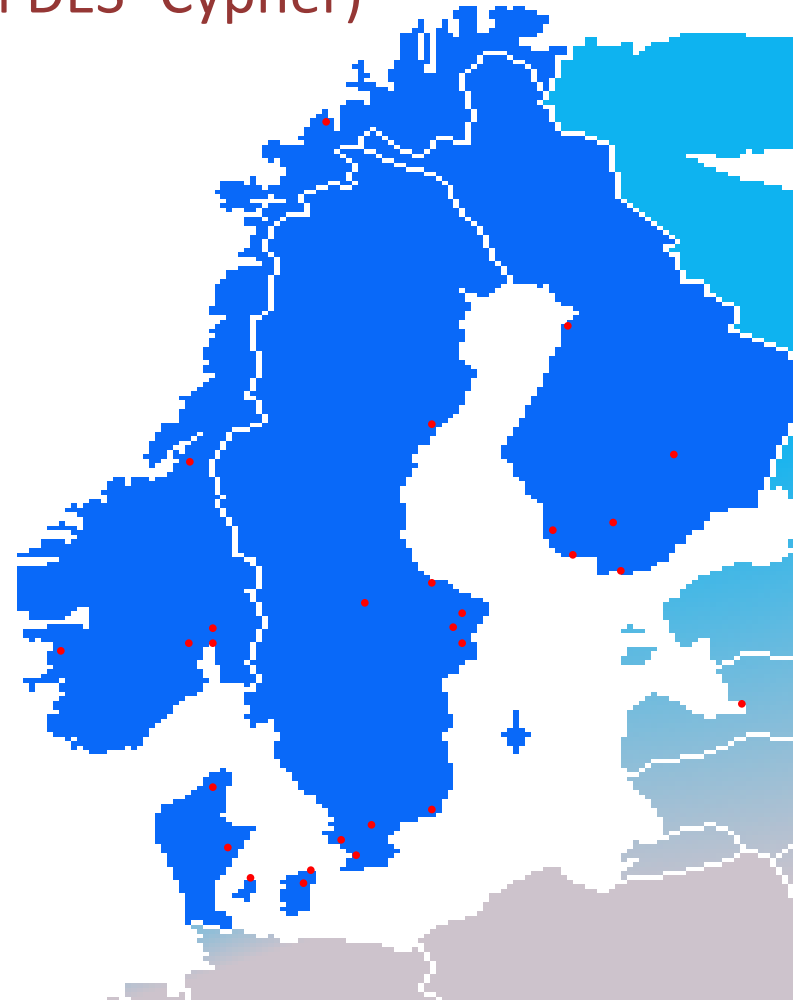
The Nordic-Baltic Bifurcation Studies were an academic studies primarily funded by participating hospitals.

The participating institutions received unrestricted study grants form Cordis .

# Nordic-Baltic Bifurcation Studies

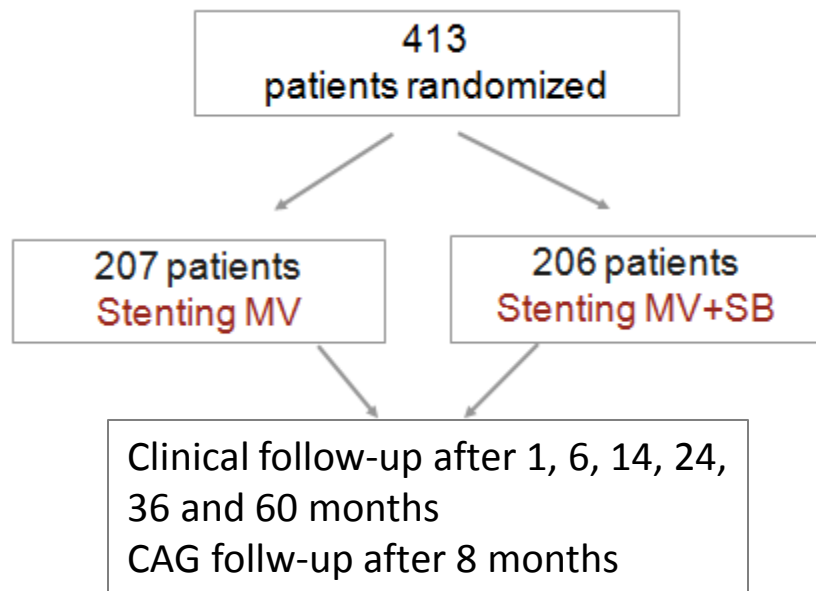
Prospective, multicenter, large-scale randomized trials  
(study device: 1st generation DES- Cypher)

- **Nordic-Baltic I**  
1 vs 2 stents
- **Nordic-Baltic II**  
Crush vs Culotte stenting
- **Nordic-Baltic III**  
+/- kissing balloon post dilatation  
after MV stenting
- **Nordic-Baltic IV**  
1 vs 2 stents in true bifurcations  
with large SB

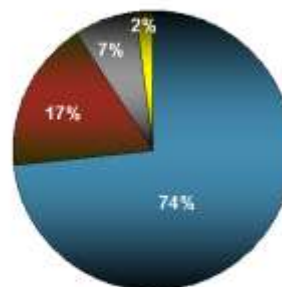


# NORDIC I

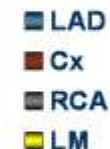
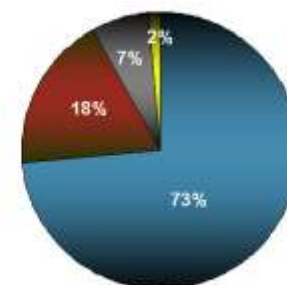
***Nordic Bifurcation Study (NORDIC I): the randomized study on simple versus complex stenting of coronary artery bifurcation lesions***



MV (n=207)



MV+SB (n=206)



**True bifurcations 71%**  
**(DS>50% in MV and SB)**

# Nordic I

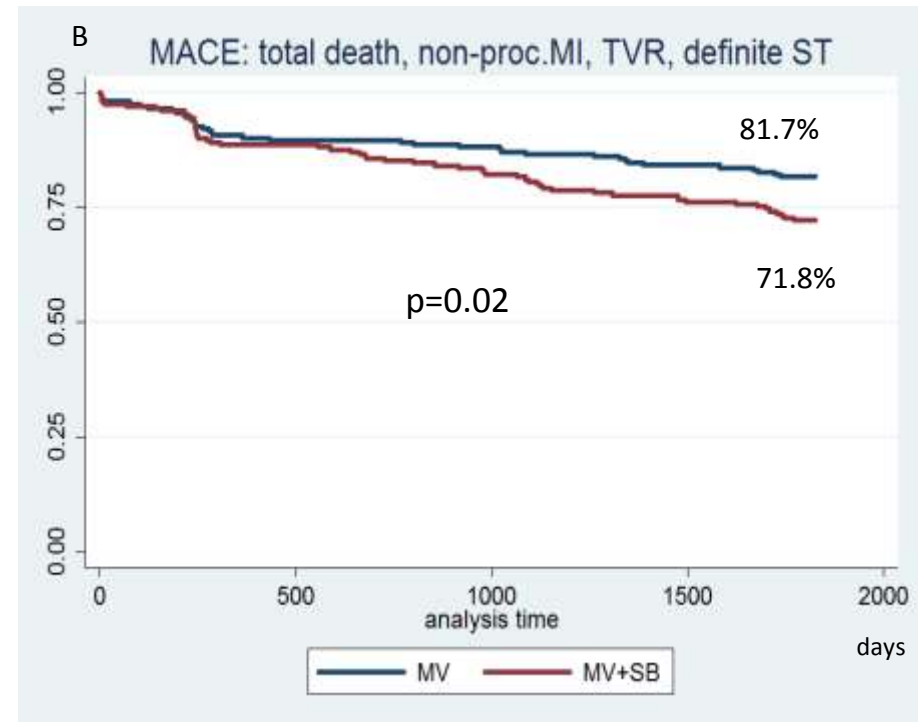
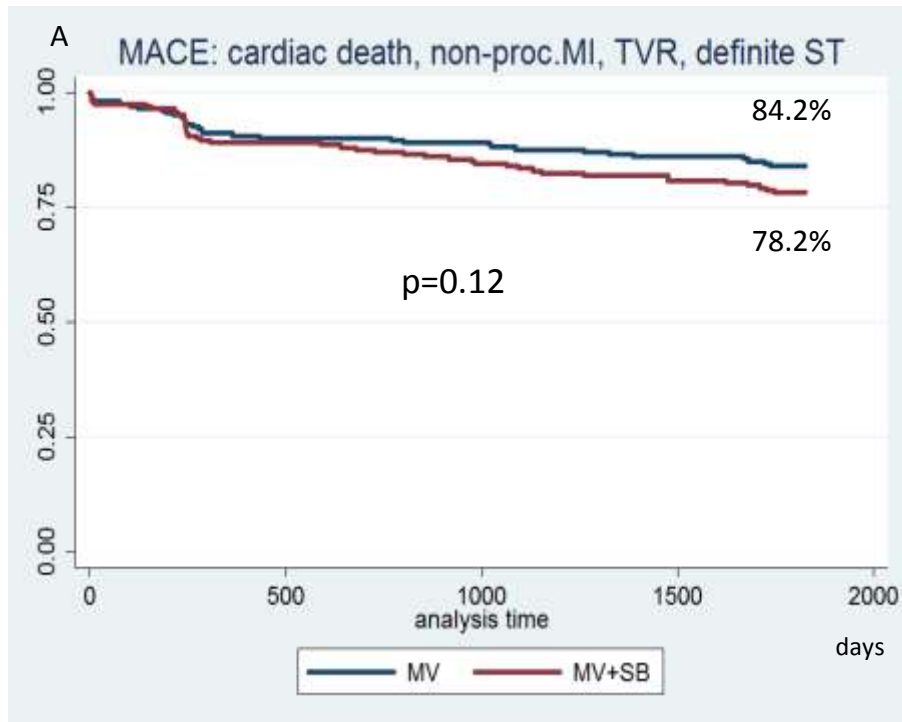
## Procedure data

Procedural Characteristics	MV n=207	MV+SB n=206	P value
MV stented	206 (99.5)	203 (98.5)	0.31
SB stented	9 (4.3)	196(95.1)	<0.0001
No. of stents	1.3±0.6	2.2±0.6	<0.0001
Final kissing balloon	<b>65 (32)</b>	<b>152 (74)</b>	<0.0001
Procedural success	200 (97)	194 (94)	0.35
Procedure time, min	62±51	76 ±40	<0.0001
Fluoroscopy time, min	15±9	21±10	<0.0001
Contrast volume, mL	233±93	283±117	<0.0001
Biomarker Elevation	n=153	n=126	P value
>3 elevation (%)	8	18	0.011
>5 elevation (%)	4	13	0.008
>10 elevation (%)	3	5	NS

# Clinical end-points at 5-year follow-up (n=404, 98%)

	MV	MV+SB	p
All cause death	5.9 %	10.4 %	0.16
Cardiac death	2.5 %	4.0 %	0.40
Myocardial infarction	4.0 %	7.9 %	0.09
Target lesion revascularization	11.3 %	15.3 %	0.24
Target vessel revascularization	13.4 %	18.3 %	0.14
Target vessel revascularization by CABG	2.0 %	3.5 %	0.38
<b>Definite stent thrombosis</b>	<b>3.0 %</b>	<b>1.5 %</b>	<b>0.32</b>

# MACE free survival at 5years follow-up

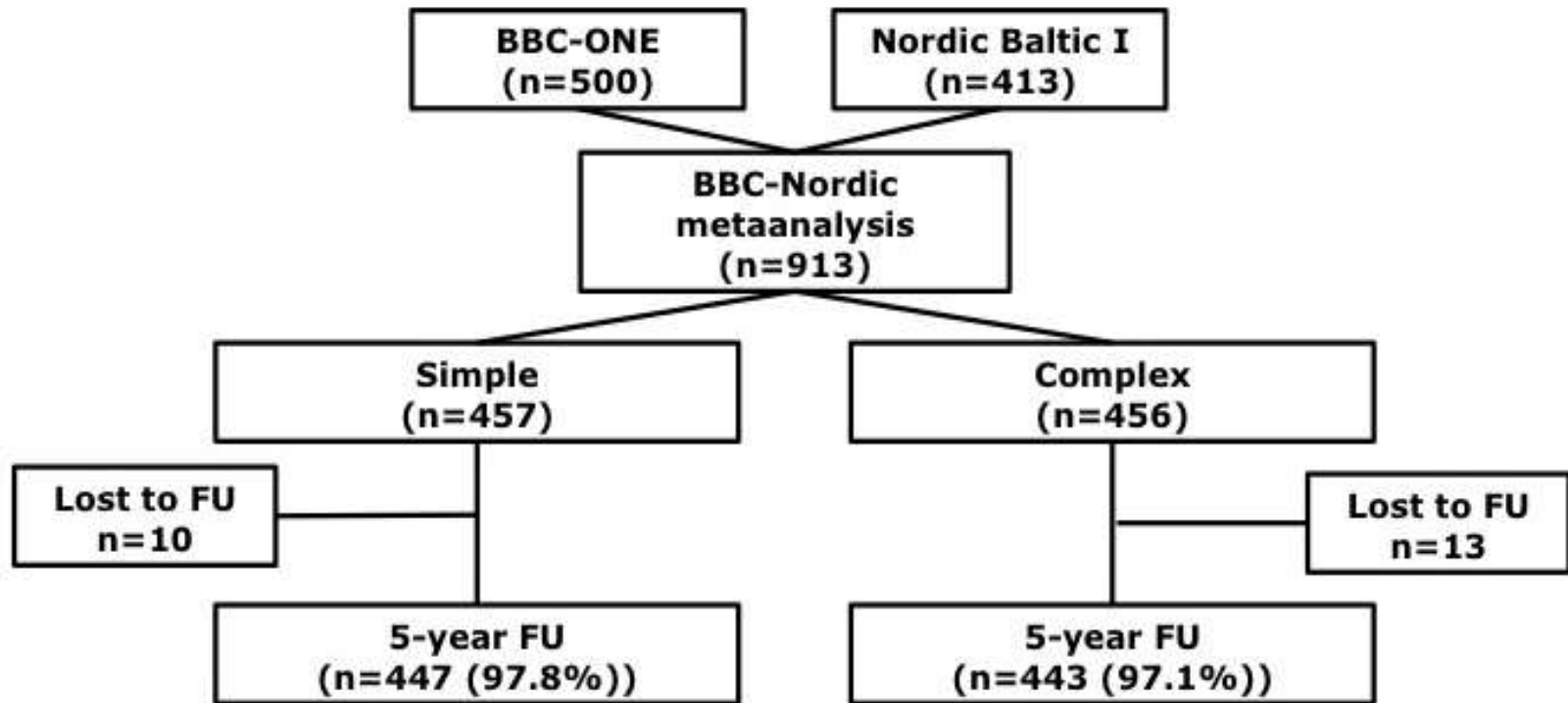


**CORONARY BIFURCATION LESIONS TREATED WITH SIMPLE OR COMPLEX STENTING:  
FIVE-YEAR SURVIVAL FROM PATIENT-LEVEL POOLED ANALYSIS OF THE  
NORDIC BIFURCATION STUDY AND THE BRITISH BIFURCATION CORONARY STUDY**

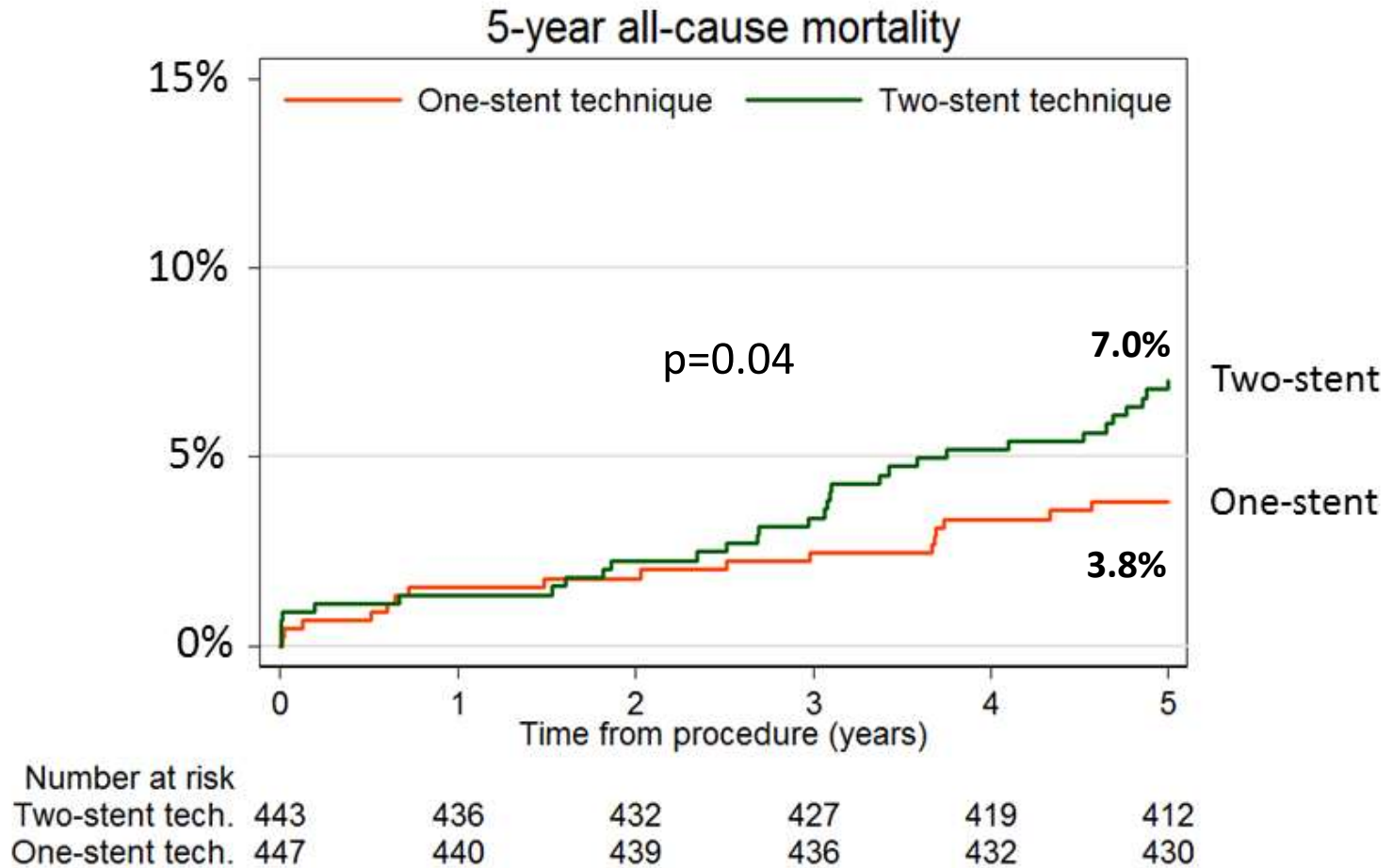
Miles W Behan, Niels R Holm, Adam J de Belder, James Cockburn, Andrejs Erglis, Nicholas P Curzen, Matti Niemelä, Keith G Oldroyd, Kari Kervinen, Indulis Kumsars, Paal Gunnes, Rodney H Stables, Michael Maeng, Jan Ravkilde, Jan Skov Jensen, Evald H Christiansen, Nina Cooter, Terje K Steigen, Saila Vikman, Leif Thuesen, Jens Flensted Lassen, David Hildick-Smith



## BBC – NORDIC I metaanalysis

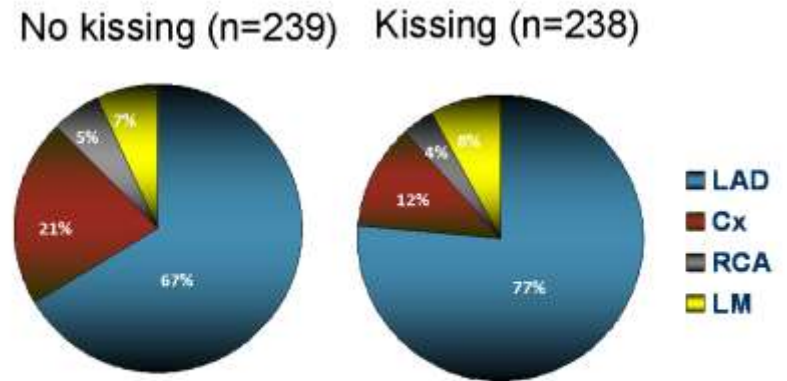
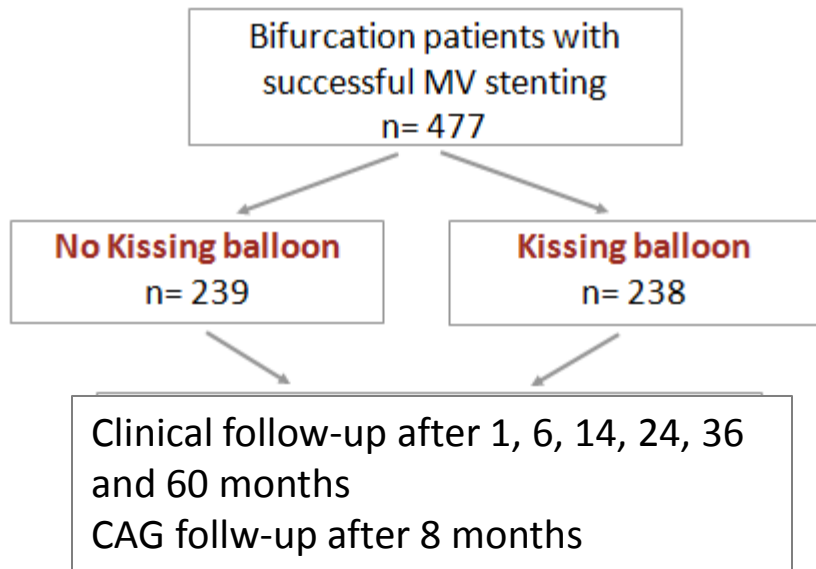


## BBC – NORDIC I metaanalysis



# NORDIC III

**Nordic-Baltic Bifurcation Study III:** A prospective randomized trial of side branch dilatation strategies in patients with coronary bifurcation lesions undergoing treatment with a single stent



True bifurcations: **50.8%** Kissing vs. **49.0%** No kissing, p=0.71

Medina classification 1,1,1 - 1,0,1 - 0,1,1

# Background

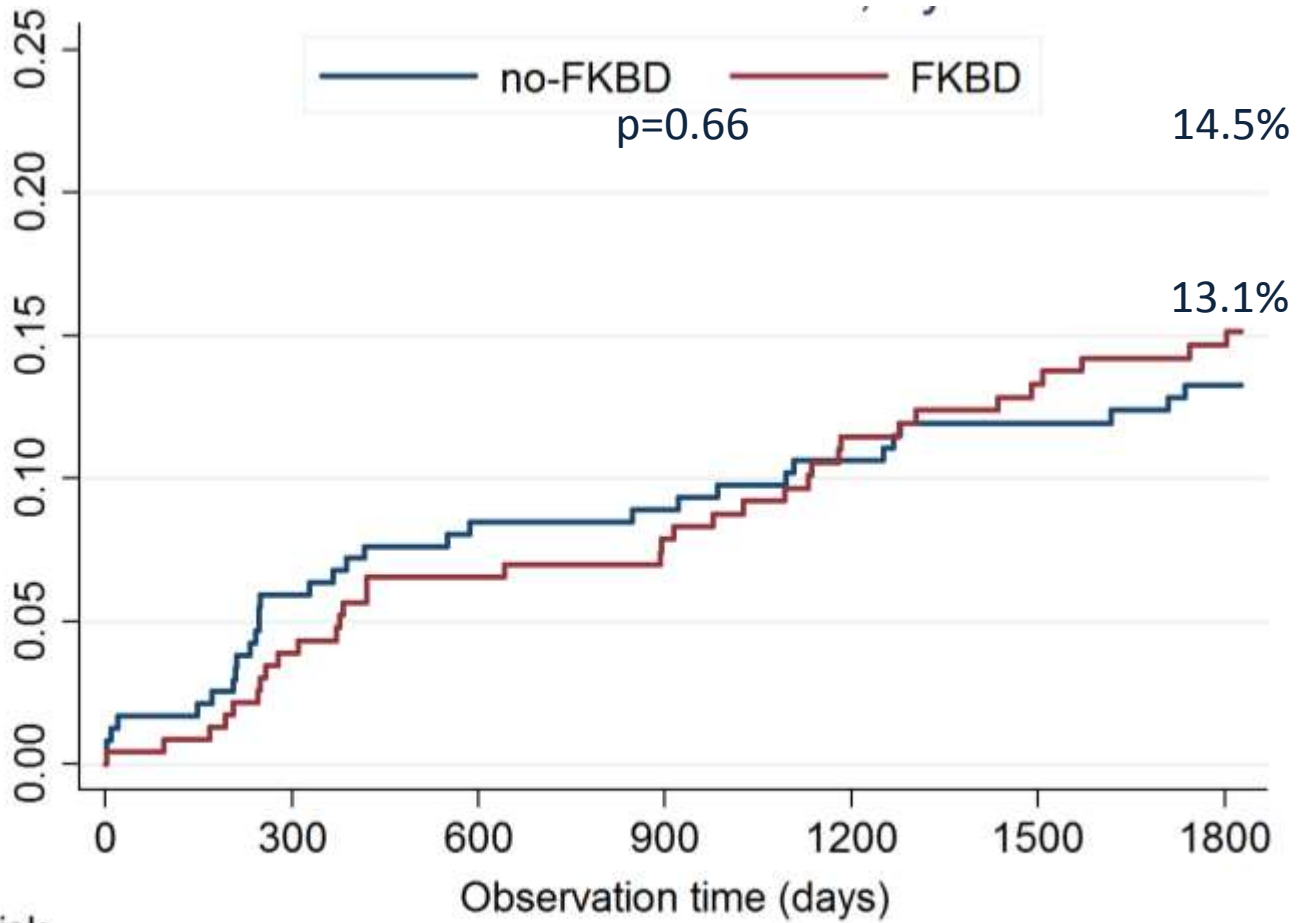
- In coronary bifurcation lesions the provisional stenting technique remains the preferred strategy in the majority of cases
- It is not known **if the main vessel stent should be routinely opened at the side branch ostium by kissing balloon dilatation** and whether leaving the side branch jailed affects long term safety

## Procedural results

	<b>No-FKBD (n=239)</b>	<b>FKBD (n=238)</b>	<b>p</b>
Procedure time (min)	47 ± 22	61 ± 28	<0.0001
Contrast volume (mL)	200 ± 92	235 ± 97	<0.0001
Flouroscopy time (min)	11 ± 10	16 ± 12	<0.0001



# Nordic-Baltic III, 5 yr MACE (n=472, 99%)

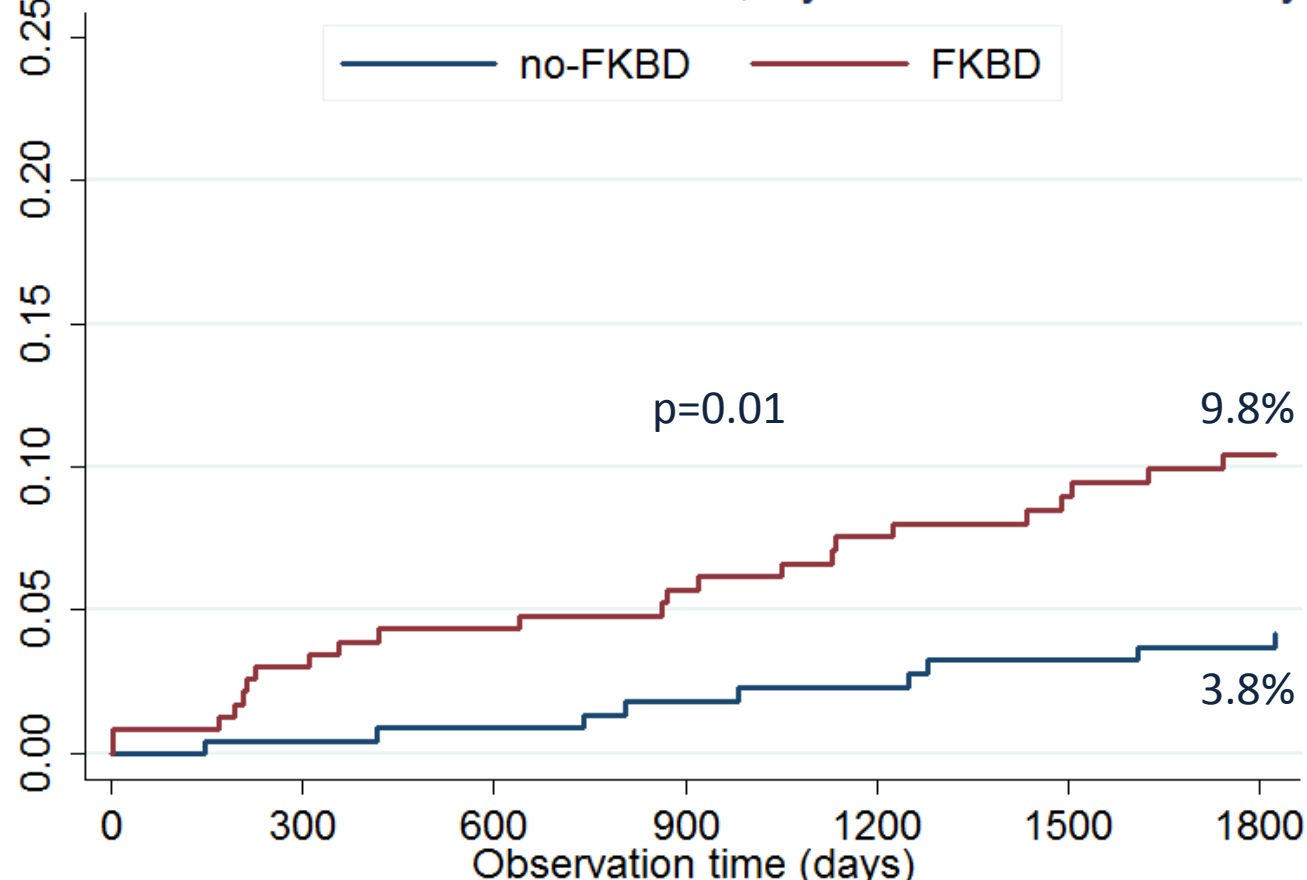


Number at risk

FKBD	235	220	212	206	196	189	184
no-FKBD	237	222	214	211	207	201	197



Nordic-Baltic bifurcation III, 5yr all-cause mortality

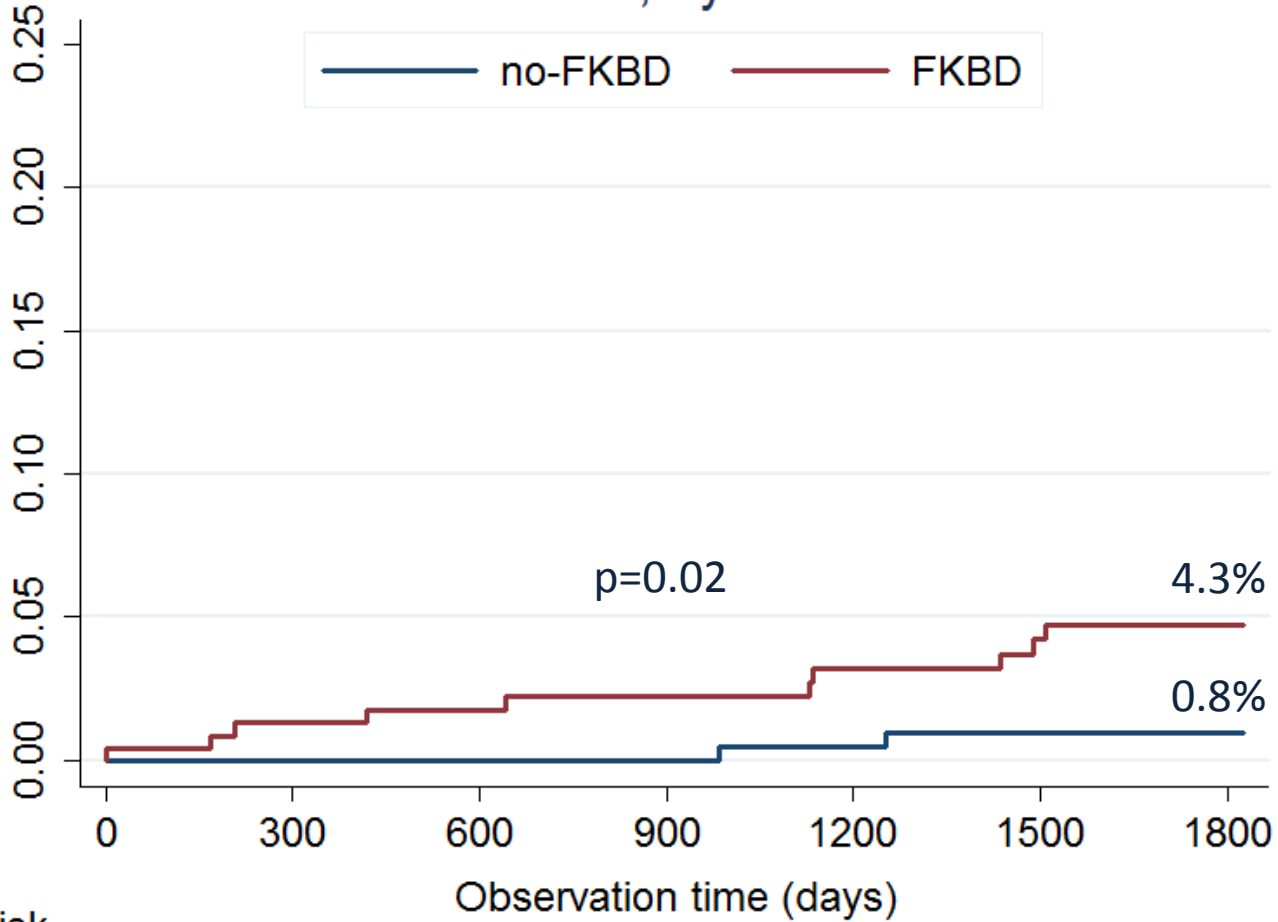


Number at risk

FKBD	235	220	212	206	196	189	184
no-FKBD	237	222	214	211	207	201	197



### Nordic-Baltic III, 5yr cardiac death

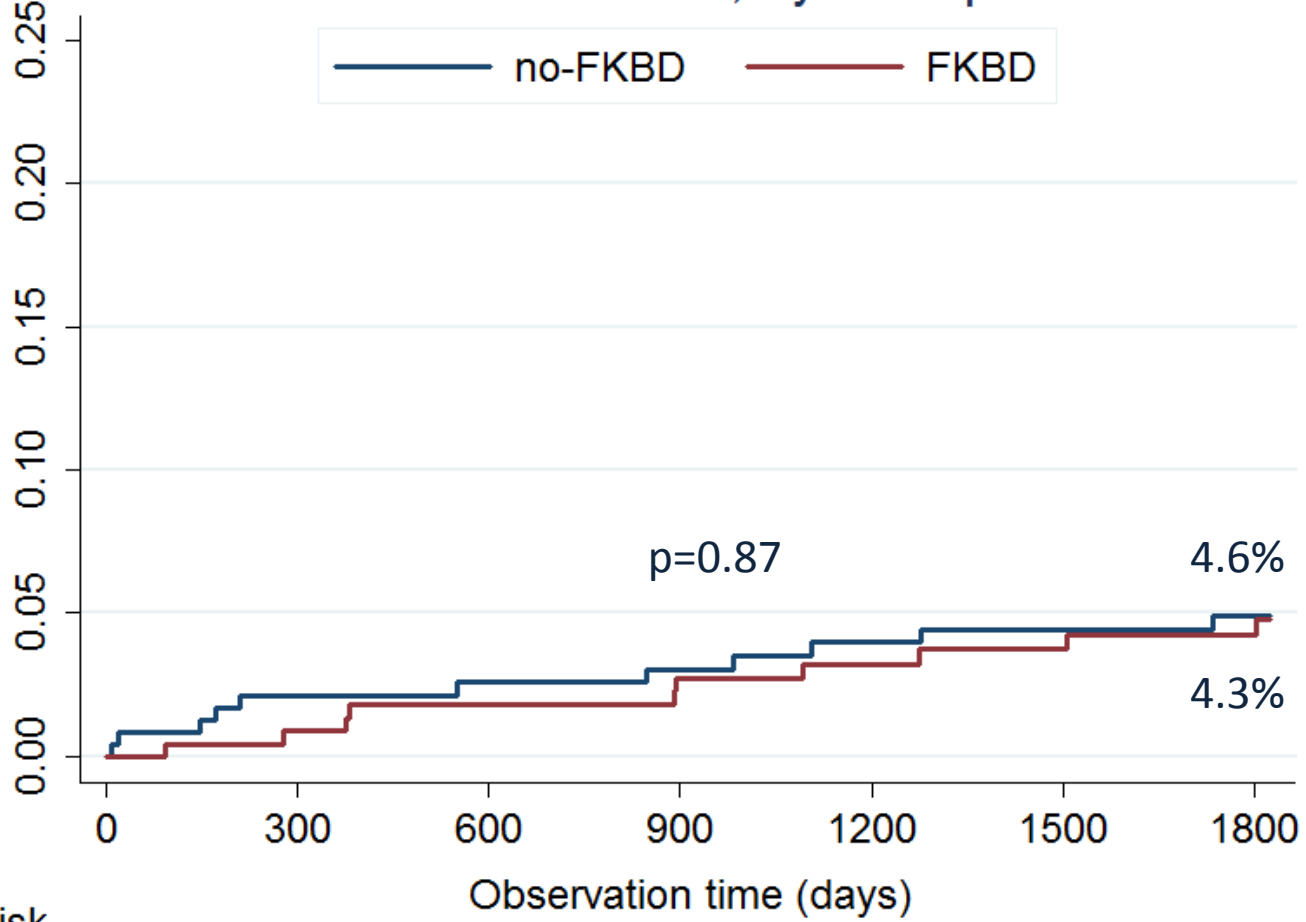


Number at risk		Observation time (days)						
		0	300	600	900	1200	1500	1800
FKBD	235	220	212	206	196	189	184	
no-FKBD	237	222	214	211	207	201	197	





Nordic-Baltic bifurcation III, 5yr non-procedural MI

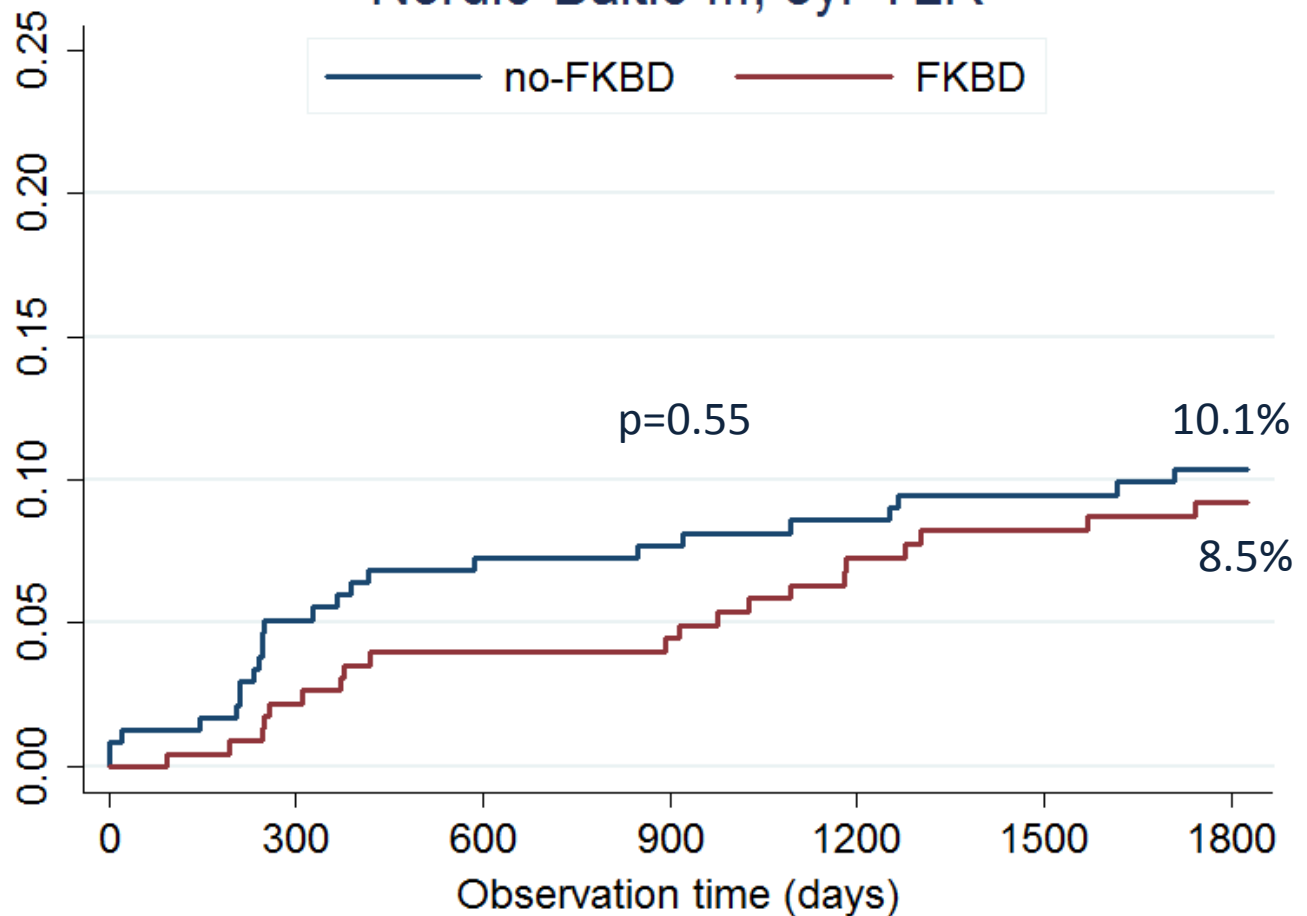


Number at risk

FKBD	235	220	212	206	196	189	184
no-FKBD	237	222	214	211	207	201	197



### Nordic-Baltic III, 5yr TLR



Number at risk

FKBD	235	220	212	206	196	189	184
no-FKBD	237	222	214	211	207	201	197

## Stent thrombosis at 5-years

	No-FKBD (n=)	FKBD (n=)	p
Stent thrombosis, definite (%)	1.3	0.8	0.66

## True bifurcation lesions

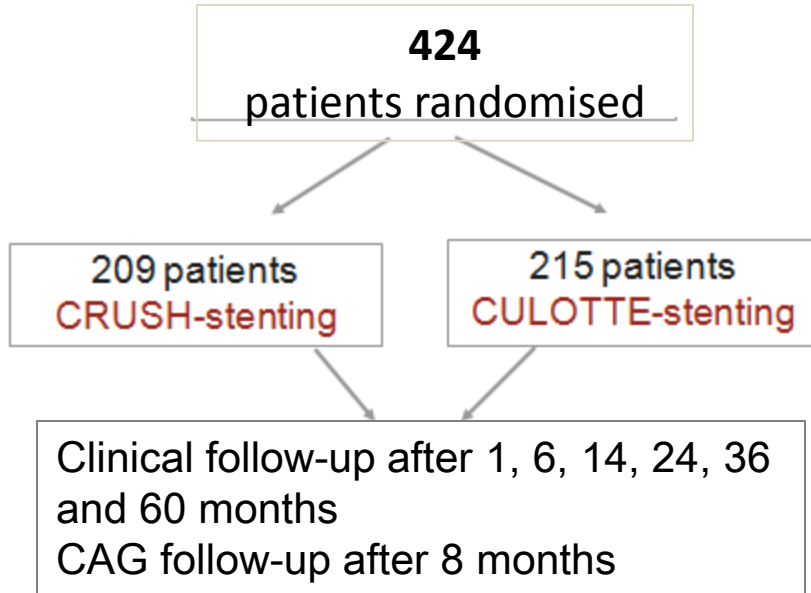
	No-FKBD (n=116)	FKBD (n=119)	p
MACE (%)	18.1	16.0	0.66
Total death (%)	3.5	8.4	0.09
Cardiac death (%)	1.7	4.2	0.23
Non-procedural MI (%)	6.0	5.9	0.96
Stent thrombosis, definite (%)	1.7	0.4	0.56
Target lesion revascularization (%)	13.8	9.3	0.19

## Non-true bifurcation lesions

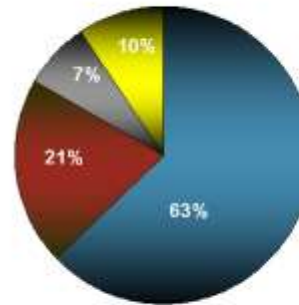
	No-FKBD (n=121)	FKBD (n=116)	p
MACE (%)	8.3	12.9	0.24
Total death (%)	4.1	11.2	0.034
Cardiac death (%)	0	4.3	0.027
Non-procedural MI (%)	3.3	2.6	0.74
Stent thrombosis, definite (%)	0.8	0	0.32
Target lesion revascularization (%)	6.6	7.7	0.346

# NORDIC II

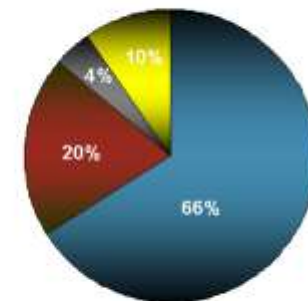
***Nordic Stent Technique Study (NORDIC II): the first randomized clinical and angiographic comparison of the crush and the culotte bifurcation stent techniques***



Crush (n=209)



Culotte (n=215)



■ LAD  
■ Cx  
■ RCA  
■ LM

**True bifurcations: 73.3% Crush vs. 82.3% Culotte, p=0.03  
(Medina classification 1,1,1 - 1,0,1 - 0,1,1)**

# Procedure data I

	CRUSH n=209	CULOTTE n=215	p-value
Aspirin Tx (%)	99.0	99.5	ns
Clopidogrel Tx (%)	99.5	100.0	ns
GPIIb/IIIa Tx (%)	46.2	47.2	ns
Bivalirudin Tx (%)	18.1	20.5	ns
Procedure time (min)	74±39	73 ± 28	ns
Fluoro time (min)	22 ± 15	22 ± 14	ns
Contrast (ml)	276 ± 104	283±117	ns

# Procedure data

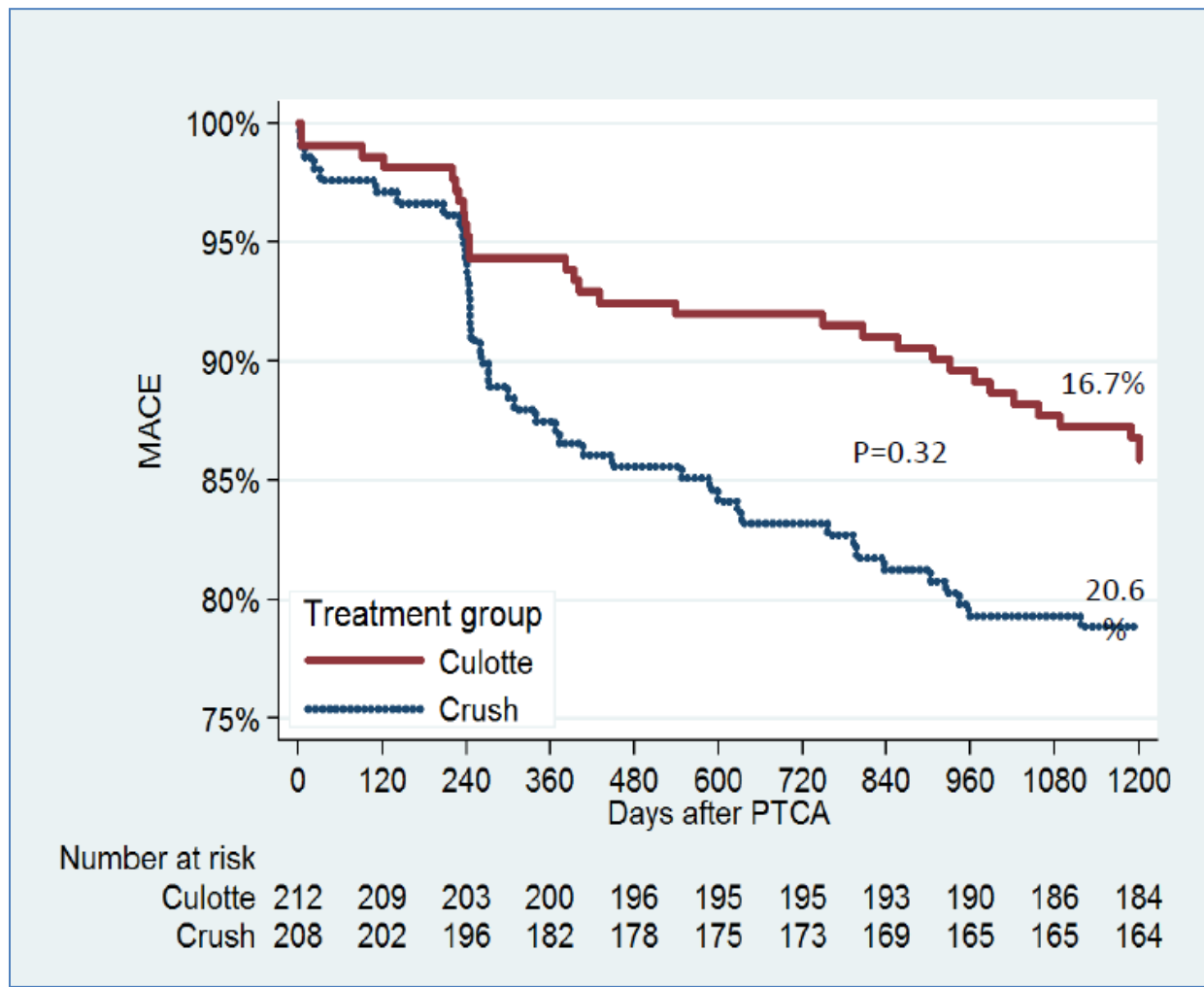
	<b>Crush n = 209</b>	<b>Culotte n = 215</b>	<b>P Value</b>
<b>MV stented, %</b>	<b>99.5</b>	<b>99.1</b>	<b>ns</b>
<b>SB stented, %</b>	<b>98.6</b>	<b>97.7</b>	<b>ns</b>
<b>Final kissing balloon</b>	<b>84.3</b>	<b>91.6</b>	<b>0.02</b>
<b>Tx acc. to ran., %</b>	<b>96.7</b>	<b>96.7</b>	<b>ns</b>
<b>Tx successful, %</b> (residual sten.<30% of MV+TIMI III flow in SB)	<b>97.6</b>	<b>97.7</b>	<b>ns</b>



# Endpoints after 3 years

	<b>Crush (n= 209)</b>	<b>Culotte (n= 215)</b>	<b>p-value</b>
Total death (%)	4.8	6.5	0.53
Cardiac death (%)	3.3	3.0	0.54
MI (%)	6.7	6.0	0.84
TLR (%)	6.2	6.1	ns
TVR (%)	12.0	9.8	0.47
Definite ST (%)	1.4	4.7	0.09
Definite, probable and possible ST (%)	5.3	7.9	0.33

# MACE free survival at 3years follow-up



# Effect of FKBD on end points

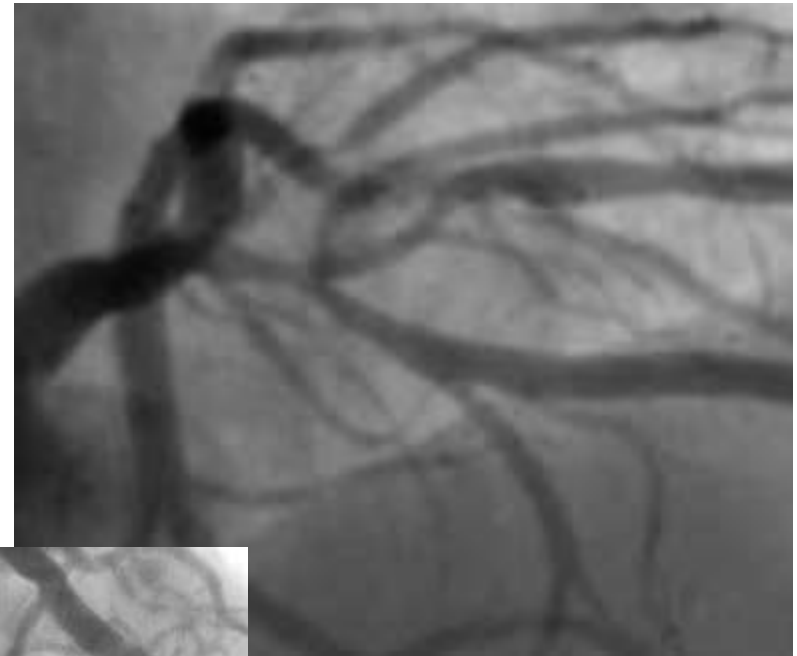
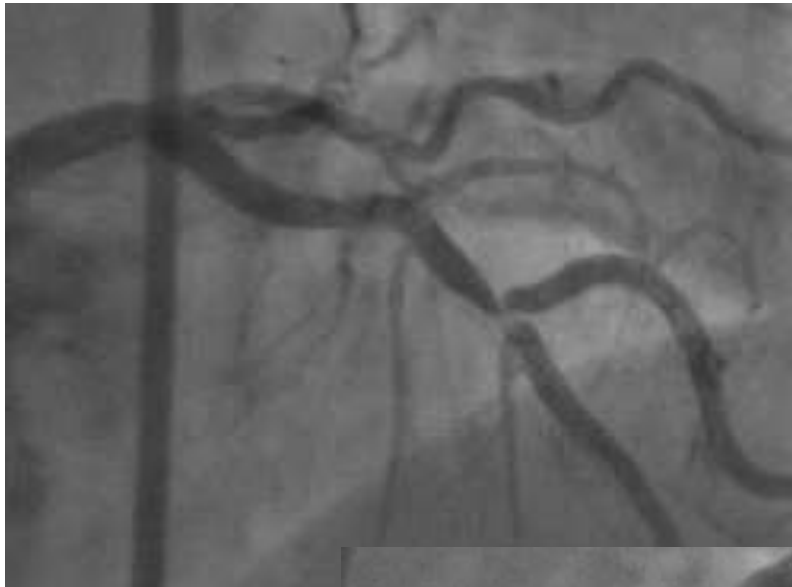
	FKBD+	No-FKBD	P-value
MACE (%)	18	24	0.3
Non-procedural MI (%)	5	18	0.001
Definite ST (%)	2	8	0.04

# The Nordic-Baltic experience

1. The long term follow-ups are very important to evaluate safety and efficacy of different stenting strategies
2. **Keep it simple!** MV stenting without final kissing balloon dilatation may be used in most cases
3. True bifurcations with a large SB may need two stents



# Medina 1,1,1 and Medina 1,1,1





Thank You for attention!